40 CFR Part 799

[OPTS-42047; FRL 2480-5]

Quinone; Proposed Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Interagency Testing Committee recommended that EPA consider requiring carcinogenicity, teratogenicity, and environmental fate testing of quinone. Under section 4(a) of the Toxic Substances Control Act (TSCA), EPA is proposing that manufacturers and processors of quinone perform testing to evaluate quinone's carcinogenic potential. Testing for teratogenicity is not being proposed because, in reviewing the existing data, the Agency has no reason to believe that quinone may present an unreasonable risk of producing teratogenic effects. EPA is not proposing to require any additional health effects testing at this time. However, EPA is proposing chemical fate and environmental effects testing because existing data indicate that effluents to surface waters may present an unreasonable risk to aquatic organisms. Chemical fate testing will establish the magnitude of the potential risk. This notice constitutes EPA's response to the Interagency Testing Committee's (ITC) designation of quinone as a priority candidate for testing.

DATES: The public is asked to submit written comments on this proposed rule on or before March 5, 1984. If persons request an opportunity for oral comment by February 21, 1984 EPA will hold a public meeting on March 19, 1984 on this rule in Washington, D.C. For further information on arranging to speak at the meeting see unit V of this preamble.

ADDRESS: Submit written comments in triplicate to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-108, 401 M St. SW., Washington, D.C. 20460.

Include the document control number [OPTS-42047] on all submissions.

FOR FURTHER INFORMATION CONTACT: Jack P. McCarthy, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. E-543, 401 M St. SW., Washington, D.C. 20460, Toll Free: (800-424-9065), in Washington, D.C.: (554-1404), outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 4(e) of TSCA (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) established an Interagency Testing Committee (ITC) to recommend to EPA a list of chemicals to be considered for testing under section 4(a) of the Act. The ITC may designate substances on the list for priority consideration for requiring testing by EPA.

The ITC designated quinone for priority consideration in its Fifth Report, published in the Federal Register on December 7, 1979 (44 FR 70664). The ITC recommended that quinone be considered for testing for carcinogenicity and teratogenicity, and also recommended that it be considered for environmental fate testing.

The ITC based its recommendation on its belief that there was potentially high exposure to humans in manufacturing and processing operations. The ITC held this assumption even considering the reported annual production of 100,000 pounds.

The ITC also had concerns about the environmental fate of quinone once it

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was released into the environment because of a potentially stable oxidation/reduction system involving quinone and hydroquinone, with a stable theoretical intermediate, semiquinone.

Under section 4(a)(1) of TSCA, EPA must require testing of a chemical substance to develop health or environmental data if the Agency finds that:

> (A) (i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,
> (ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and
> (iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or
> (B) (i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,
> (ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and
> (iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

EPA uses a weight of evidence approach in making a section 4(a)(1)(A)(i) finding in which both exposure and toxicity information are considered to make the finding that the chemical may present any unreasonable risk. For the section 4(a)(1)(B)(i) finding, EPA considers only production, exposure and release information to determine if there is or may be substantial production and substantial or significant exposure or substantial release. For the findings under both sections 4(a)(1)(A)(ii) and 4(a)(1)(B)(ii), EPA examines toxicity and fate studies to determine if existing information is adequate to reasonably determine or predict the effects of human exposure to, or environmental release of, the chemical. In making the third finding, that testing is necessary, EPA considers whether any ongoing testing will satisfy the information needs for the chemical and whether testing which the Agency might require would be capable of developing the necessary information.

EPA's process for determining when these findings apply is described in detail in EPA's first and second proposed test rules. The section 4(a)(1)(A) findings are discussed in the **Federal Register** of July 18, 1980 (45 FR 48528) and June 5, 1981 (46 FR 30300) and the section 4(a)(1)(B) findings are discussed in the **Federal Register** of June 5, 1981 (46 FR 30302).

In evaluating the ITC's testing recommendations for quinone, EPA considered all available relevant information including the following: information presented in the ITC's report recommending testing consideration; production volume, use, exposure, and release information reported by manufacturers of quinone under the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR Part 712); unpublished health and safety studies submitted by the manufacturers of quinone under the TSCA section 8(d) Health and Safety Data Reporting Rule (40 CFR Part 716); and other published and unpublished data available to the Agency. On the basis of its evaluation, as described in this proposed rule and the accompanying technical support document, EPA is proposing oncogenicity, chemical fate, and environmental effects testing requirements for quinone under section 4(a)(1)(A) of TSCA. By these actions, EPA is responding to the ITC's designation of quinone for testing consideration.

II. Proposed Rule

A. Profile

Quinone ($C_6H_4O_2$), CAS No. 106-51-4, is a yellow crystalline solid at room temperature, is slightly soluble in water, and is soluble in ethanol, ether, and hot petroleum ether. It acts chemically as an oxidizing agent and, in aqueous solution, is reduced to hydroquinone by sulfur dioxide. The EPA Toxic Substances Inventory records that from 100,000 to 1,000,000 pounds of quinone were produced in the United States in 1977.

Quinone is primarily used as an intermediate in the production of hydroquinone. Because quinone is a very good oxidizing agent, it is used as a bleach for silver in photographic processes. It is also used as an inhibitor of polymerization, as a tanning agent, and as an intermediate in the synthesis of other chemicals.

B. Findings

1. EPA is basing its proposed health effects testing on the authority of section 4(a)(1)(A) of TSCA. Based upon the facts stated below, EPA finds that quinone may present an unreasonable risk of injury to human health and that there are insufficient data and experience to reasonably determine or predict the carcinogenic potential of quinone. Therefore, testing is needed to obtain these data.

a. EPA has determined that existing data indicate a potential human health hazard from quinone with respect to carcinogenic effects. Two studies have suggested the induction of malignant adenomas in mice after prolonged inhalation, and another has reported sarcomas in rats after subcutaneous exposure. While these studies have limited quality, they do suggest that quinone may have carcinogenic potential.

b. EPA believes that persons are exposed to quinone in the workplace, both in manufacturing and processing activities at levels that may lead to carcinogenic effects. In 1980, the National Institute for Occupational Safety and Health (NIOSH) estimated that annually about 3,700 U.S. workers, in nine occupations, are potentially exposed to quinone. Therefore, based on the Agency's review and analyses of the information at its disposal, EPA is proposing that quinone be tested for carcinogenic effects.

2. The Agency is basing its chemical fate and environmental effects testing on the authority of section 4(a)(1)(A) of TSCA. The ITC proposed that chemical fate testing be conducted with quinone to establish the stability of the quinone-semiquinone-hydroquinone oxidation-reduction system in the environment. EPA finds that there is evidence of potential unreasonable environmental risks to aquatic organisms resulting from exposure to quinone.

a. The levels of quinone that may be found in receiving waters after

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treatment efforts are very close to the quinone levels that have been found to be acutely toxic to two aquatic species. While the existing exposure and environmental effects data suggest these concerns, these data are inadequate to reasonably predict or determine the actual effects of these exposures of aquatic organisms to quinone. Therefore, testing is needed to obtain these data.

b. The Agency believes that hydroquinone is released to surface waters from photoprocessing operations and that a substantial portion of this material is converted to quinone. EPA also believes that the levels of hydroquinone in these effluents may be high enough that, when converted, the resulting levels of quinone would pose an unreasonable risk to freshwater and saltwater aquatic species. This conclusion is based on existing aquatic organism toxicity data. Additional environmental effects testing is needed to assess the types of organisms potentially at risk.

c. The Agency is also proposing chemical fate testing for quinone. EPA believes this testing is essential because the existing chemical fate data are limited and additional data are needed to assess the magnitude of the possible risks to aquatic organisms. EPA needs additional information to establish biodegradation rates in order to assess the levels of exposure of aquatic organisms to quinone.

3. EPA does not believe that the rule will result in a loss to society of the benefits of quinone because the Agency's economic evaluation has shown that the economic impact of testing this substance will be minimal.

The analyses on which these findings are based are presented in the Technical Support Document "Assessment of Testing Needs: Hydroquinone/Quinone" which was developed for this rulemaking and is available from the TSCA Assistance Office (TAO). The ITC recommendations and EPA's proposed testing requirements are summarized in the following Table.

TABLE—TESTING RECOMMENDATIONS FOR QUINONE

Test or study	ITC recommendation	EPA proposal
Carcinogenicity	X	X
Teratogenicity	X	
Environmental fate	X	X
Environmental effects		X

The Agency is not proposing teratogenicity testing for quinone. Although teratogenicity testing was proposed by the ITC, EPA has not identified any data that provide sufficient evidence under section 4(a)(1)(A) of TSCA that quinone may present an unreasonable risk of causing teratogenic effects.

C. Test Substance

EPA is proposing that quinone of at least 99 percent purity be used as the test substance in the carcinogenicity, chemical fate and environmental effects testing. EPA has specified a relatively pure substance for testing because the Agency is interested in evaluating the effects attributable to quinone itself. This requirement would increase the likelihood that any toxic effects observed are related to quinone and not to any impurities.

D. Persons Required to Test

Section 4(b)(3)(B) specifies that the activities for which the Administator makes section 4(a) findings (manufacture, processing, distribution, use, and/or disposal) determine who bears the responsibility for testing. Manufacturers are required to test if the findings are based on manufacturing ("manufacture" is defined in section 3(7) of TSCA to include "import"). Processors are required to test if the findings are based on processing. Both manufacturers and processors are required to test if the exposures giving rise to the potential risk occur during use, distribution, or disposal. Because EPA has found that the manufacture, processing, disposal, and use of quinone may present an unreasonable risk to human health and the environment, EPA is proposing that persons who manufacture or process, or who intend to manufacture or process, quinone at any time from the effective date of this test rule to the end of the reimbursement period be subject to the rule. The end of the reimbursement period ordinarily will be 5 years after the submission of the last final report required under the test rule.

Because TSCA contains provisions to avoid duplicative testing, not every person subject to this rule must individually conduct testing. Section 4(b)(3)(A) of TSCA provides that EPA may permit two or more manufacturers or processors who are subject to the rule to designate one such person or a qualified third person to conduct the tests and submit data on their behalf. Section 4(c) provides that any person required to test may apply to EPA for an exemption from that requirement (as discussed in Unit II F. below).

E. Approach to Adoption of Test Rules

1. *General Process.* On March 26, 1982, EPA announced a new approach to adoption of test rules (47 FR 13102). EPA intends to promulgate a general procedural rule in 40 CFR Part 770 which will contain the procedural requirements of this new approach. However, since that procedural rule is not in effect, this proposed rule contains specific procedures for adoption of this test rule. If the general rule is promulgated before this proposal becomes final, the quinone rule will be modified to comport with the general procedural provisions.

Under the approach being followed for quinone, test rule development will be a two-phase process. In phase I, EPA will propose that specific testing be required for quinone. This phase of the rulemaking will allow the public to comment on the decision to require testing and the specific types of tests to be required. Phase II begins after promulgation of the phase I rule. In phase II, EPA will receive proposed study plans for the specific tests adopted in the phase I rule. EPA will propose those study plans for public comment. After comment, the Agency will adopt the study plans, as proposed or modified, as specific test standards for the tests required by the phase I rule. Persons who submit the study plans will be obligated to perform the tests in accordance with the test standards adopted.

2. *Letter of Intent to Test or Exemption Application.* The proposed rule would require manufacturers and processors of quinone to perform certain tests. Once the rule is in effect, 30 days after publication in the Federal Register, each current manufacturer would have 30 days to submit, for each required test in paragraphs (i), (j) and (k) of the rule, either a letter of intent to perform the test or an application for exemption. Each manufacturer who submitted a letter of intent to perform a specific test would be obligated, first, to submit, within 90 days of the effective date, a proposed study plan for the test and, ultimately, to perform the testing.

If manufacturers of quinone performed all the required tests, processors of quinone would not be required to test or to submit exemption applications. EPA would automatically grant them exemptions from the requirements of the rule.

If no manufacturer of quinone submitted a letter of intent to perform a particular test within the 30-day period, EPA would publish a notice in the Federal Register to notify all processors of quinone. The notice would state that EPA had not received letters of intent to perform certain tests and that current processors would have 30 days to submit, for each test remaining, either a

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letter of intent to perform the test or an exemption application for that test. Each processor who submitted a letter of intent to perform a specific test would be obligated, first, to submit, within 90 days of the publication of the Federal Register notice, a proposed study plan for the test and, ultimately, to perform the testing.

If no manufacturer or processor submitted a letter of intent to perform a particular test, EPA would notify all manufacturers and processors, by letter or through the Federal Register, that all exemption applications would be denied and that within 30 days all manufacturers and processors would be in violation of the rule until a proposed study plan is submitted for that test.

Any person not manufacturing quinone at the time the rule goes into effect, who later begins manufacturing before the end of the reimbursement period, would be required to submit a letter of intent to test or an exemption application for each required test by the day the person begins manufacture. If EPA has published a notice in the Federal Register telling processors to submit letters of intent or exemption applications for certain test, any person not processing quinone at the time the rule goes into effect, who later begins processing before the end of the reimbursement period, would be required to submit a letter of intent to test or an exemption application for each test specified in the Federal Register notice by the day the person begins processing.

3. *Submission and Adoption of Study Plans.* Any manufacturer of quinone who submitted a letter of intent to perform a test would have to submit, within 90 days after the effective date of the rule, a proposed study plan for that test. In the event manufacturers do not submit letters of intent for all the required tests, any processor who submits a letter of intent to perform a specific test would have to submit, within 90 days of the publication of the Federal Register notice notifying processors, a proposed study plan for that test. Paragraph (e) or the rule describes the contents of a proposed study plan.

EPA proposed generic test methodology requirements (generic test standards) in the Federal Register of May 9, 1979 (44 FR 27334) July 26, 1979 (44 FR 44054) and November 21, 1980 (45 FR 77332). In response to concerns about the rigidity of generic methodology requirements, EPA has changed its approach for providing test standards for TSCA section 4 test rules. It has issued generic test methodology guidelines to replace the previously proposed generic test methodology requirements. The TSCA guidelines have been published by the National Technical Information Service (NTIS) for health effects (PB 82-232984), for chemical fate, (PB 82-233008) and for environmental effects (PB 82-232992), respectively. Good Laboratory Practice (GLP) Standards for development of data on health effects of chemical substances under TSCA were proposed in the Federal Register of May 9, 1979 (44 FR 27334) and July 26, 1979 (44 FR 44054), and for chemical fate and environmental effects testing in the Federal Register of November 21, 1980 (44 FR 77357). GLP standards for development of data on physical and chemical properties, persistence, and ecological effects of chemical substances under TSCA were proposed in the Federal Register of November 21, 1980 (44 FR 77357). These GLP standards will be promulgated as generic requirements. The final TSCA GLP regulations will apply to the quinone test rule.

For guidance in preparing study plans, EPA recommends that test sponsors consult the TSCA Test Guidelines and the TSCA GLP standards as referenced above; the Organization for Economic Coöperation and Development's (OECD) Guidelines, as adopted by the OECD Council on May 12, 1981; or the FIFRA Pesticide Registration Guidelines: Proposed Data Requirements, published by the National Technical Information Service (see the Federal Register of November 24, 1982 (47 FR 53192), for a list of these guidelines).

Failure to submit a study plan would be a violation of the rule.

EPA would review the proposed study plans. If they are incomplete, the manufacturer or processor would be notified of the deficiency and would have 15 days to provide appropriate information to make the plan complete. If the information is not provided in 15 days, the manufacturer or processor would be in violation of the rule. In addition, EPA would return to the appropriate stage of the process and require maufacturers or processors, as appropriate, to submit letters of intent, exemption applications, and study plans.

If the proposed study plan is complete, EPA would propose the study plan for public comment. In particular, the request for comments would focus on whether the study plan will ensure that data from the test will be reliable and adequate. There would be a 45-day comment period and the opportunity to present views orally upon request. After considering the public comment, EPA would adopt the study plans as proposed, or as modified in response to comment, as the test standard for the required test.

The person who submitted the proposed study plan would be required to perform the testing according to that standard. Failure to perform the testing would be a violation of the rule.

F. Exemptions

EPA's proposed policy on application for exemptions from section 4 testing requirements was published in the Federal Register of July 18, 1980 (45 FR 48512). EPA intends to promulgate its final procedures for exemptions in 40 CFR Part 770. The exemption procedures described below and included in the proposed rule language are consistent with EPA's current thinking on exemption procedures. If the general rule is promulgated before this proposal becomes final, the quinone rule will be modified to comport with the general procedural provisions.

Any manufacturer or processor of quinone would be able to apply for an exemption. Any person who has applied for an exemption would not be in violation of the rule until such time as EPA denies the application.

If manufacturers perform all the required testing, processors would be granted exemptions automatically without having to file applications.

When EPA has received a proposed study plan for a test and has adopted the plan as the test standard, EPA would conditionally grant all exemption applications for that test. If the test sponsor later fails to perform the test, EPA would notify all persons who had submitted exemption applications for that test that the exemptions would be denied, unless within 30 days a manufacturer or processor notified EPA of its intent to perform the test in accordance with the adopted test standards.

EPA is not proposing to require the submission of equivalence data as a condition for exemption from the proposed testing for quinone. As noted in Unit II.C., EPA is interested in evaluating the effects attributable to quinone itself and has specified a relatively pure substance for testing.

G. Reporting Requirements

EPA is proposing that all data developed under this rule be reported in accordance with the TSCA GLP standards which will appear in 40 CFR Part 792.

EPA is required by TSCA section 4(b)(1)(C) to specify the time period during which persons subject to a test rule must submit test data. These

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deadlines will be established in the phase II rulemaking in which study plans are approved.

TSCA section 14(b) governs Agency disclosure of all test data submitted pursuant to section 4 of TSCA. Upon receipt of data required by this rule, the Agency will publish a notice of receipt in the **Federal Register** as required by section 4(d).

H. Enforcement Provisions

The Agency considers failure to comply with any aspect of a section 4 rule to be a violation of section 15 of TSCA. Section 15(1) of TSCA makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to: (1) Establish or maintain records, (2) submit reports, notices, or other information, or (3) permit access to or copying of records required by the Act or any rule issued under TSCA.

Additionally, TSCA section 15(4) makes it unlawful for any person to fail or refuse to permit entry or inspection as required by section 11. Section 11 applies to any "establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce. . . ." The Agency considers a testing facility to be a place where the chemical is held or stored, and therefore, subject to inspection. Laboratory audits/inspections will be conducted periodically in accordance with the authority and procedures outlined in TSCA section 11 by duly designated representatives of EPA for the purpose of determining compliance with any final rule for quinone. These inspections may be conducted for purposes which include verification that testing has begun, that schedules are being met, that reports accurately reflect the underlying raw data and interpretations and evaluations thereof, and that the studies are being conducted according to EPA GLP standards and the protocols established in the phase II rule.

EPA's authority to inspect a testing facility also derives from section 4(b)(1) of TSCA, which directs EPA to promulgate standards for the development of test data. These standards are defined in section 3(12)(B) of TSCA to include those requirements necessary to assure that data developed under testing rules are reliable and adequate, and such other requirements as are necessary to provide such assurance. The Agency maintains that laboratory inspections are necessary to provide this assurance.

Violators of TSCA are subject to criminal and civil liability. Persons who submit materially misleading or false information inconnection with the requirement of any provision of this rule may be subject to penalties calculated as if they never submitted their data. Under the penalty provision of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty of up to $25,000 per day for each violation, with each day of operation in violation constituting a separate violation. This provision would be applicable primarily to manufacturers or processors that fail to submit a letter of intent to perform testing or an exemption request, and that continue manufacturing or processing after the deadlines for such submissions. Knowing or willful violations could lead to the imposition of criminal penalties of up to $25,000 for each day of violation and imprisonment for up to one year. Other remedies are available to EPA under section 17 of TSCA, such as seeking an injunction to restrain violations of TSCA section 4.

Individuals as well as corporations could be subject to enforcement actions. Sections 15 and 16 of TSCA apply to "any person" who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies themselves. In particular, this includes individuals who report false information or who cause it to be reported. In addition, the submission of false, fictitious, or fraudulent statements is a violation under 18 U.S.C. 1001.

I. Issue for Public Comment

As indicated in the Technical Support Document for Hydroquinone/Quinone, the Agency believes that the presence of quinone in the environment is primarily a result of the release of hydroquinone which is converted to quinone in the environment. The Agency is proposing environmental effects and chemical fate testing for quinone as well as environmental effects and chemical fate testing for hydroquinone. As proposed, manufacturers and processors of quinone would be responsible for testing quinone for environmental effects, regardless of the fact that most quinone in environment might result from releases of hydroquinone.

Requiring manufacturers and processors of quinone to conduct environmental effects and chemical fate testing of quinone may be inequitable if the quinone in the environment results primarily from hydroquinone manufacture and processing. However, section 4(b)(3)(B) of TSCA specifies that testing must be conducted by "[e]ach person who manufactures or intends to manufacture *such substance*" and "[e]ach person who processes or intends to process *such substance*." EPA believes that this language requires the approach contained in the proposal for quinone testing. However, the Agency is considering requiring the manufacturers and processors of hydroquinone to either conduct or share in the cost of conducting environmental effects and chemical fate testing for quinone. This could be accomplished either by transferring the quinone environmental effects and chemical fate testing requirements to the hydroquinone test rule or by adding manufacturers and processors of hydroquinone to those required to test under the quinone test rule. EPA solicits comments on these alternative approaches to testing quinone for chemical fate and environmental effects.

III. Economic Analysis of Proposed Rule

To evaluate the potential economic impact of this proposed rule, EPA has prepared a Level I economic analysis that examines the costs of the required testing and analyzes four principal market characteristics of the chemical substance: (1) Demand sensitivity, (2) cost characteristics, (3) industry structure, and (4) market expectations.

The Level I analysis of quinone, which estimates the total testing costs to range from $322,200 to $975,800, indicates that the potential for adverse economic effects due to the estimated testing costs is low. This conclusion is based on the following observations:

1. Stable or moderate market growth is expected for quinone.

2. The relative magnitude of the test cost is minor, i.e., on an annual unit cost basis, the test costs are estimated to average 0.5–1.4 cents per pound. The unit costs represent 0.1 to 0.3 percent of the price of quinone.

3. Since most of the quinone produced is used for the production of hydroquinone, most of the cost of testing quinone will be passed on to the consumers of hydroquinone.

4. Because the market for hydroquinone is stable or growing somewhat and demand in its primary uses is inelastic, it appears the indirect cost of quinone testing can be passed on to consumers with little or no economic impact.

Because the Level I analysis indicates very little potential for an adverse economic impact, EPA has determined that a more comprehensive and detailed Level II economic analysis is not needed for quinone.

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IV. Availability of Test Facilities and Personnel

Section 4(b)(1) of TSCA requires EPA to consider "the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule." Therefore, EPA conducted a study to assess the availability of test facilities and personnel to handle the additional demand for testing services created by section 4 test rules and test programs negotiated with industry in place of rulemaking. Copies of the study, "Chemical Testing Industry: Profile of Toxicological Testing," October, 1981, can be obtained through the NTIS (PB 82-140773).

On the basis of this study, the Agency believes that there will be available test facilities and personnel to perform the testing in this proposed rule.

V. Public Meetings

If persons indicate to EPA that they wish to present comments on this proposed rule to EPA officials who are directly responsible for developing the rule and supporting analyses, EPA will hold a public meeting on March 19, 1984 in Washington, D.C. Persons who wish to present comments at the meeting should call the TSCA Assistance Office (TAO), Toll Free: (800-424-9065). In Washington, D.C.: (554-1404). Outside the U.S.A.: (Operator 202-554-1404), by February 21, 1984. The meeting will not be held if members of the public do not indicate they wish to make oral presentations. This meeting is scheduled after the deadline for submission of written comments, so that issues raised in the written comments can be discussed by EPA and the public commenters. While the meeting will be open to the public, active participation will be limited to those persons who arranged to present comments and to designated EPA participants. Attendees should call the TAO before making travel plans to check whether the meeting will be held.

Should a meeting be held, the Agency will transcribe the meeting and include the written transcript in the public record. Participants are requested, but not required, to submit copies of their statements prior to or on the day of the meeting. All such written materials will become part of EPA's record for this rulemaking.

VI. Rulemaking Record

EPA has established a record for this rulemaking, docket number [OPTS-42047]. This record includes the basic information the Agency considered in developing this proposal, and appropriate Federal Register notices. The Agency will supplement the record with additional information as it is received. Confidential business information (CBI), while part of the record, is not available for public review. A public version of the record, from which CBI has been deleted, is available for inspection in the OPTS Reading Room from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays, in Rm. E-107, 401 M St. SW., Washington, D.C.

The record includes the following information:

(1) Federal Register notices pertaining to this rule making consisting of:

(a) Notice of proposed rulemaking on quinone.

(b) Notice containing the ITC designation of quinone to the Priority List [44 FR 70664, December 7, 1979].

(c) Notices relating to EPA's health effects, chemical fate, and environmental effects (44 FR 27334, May 9, 1979; 44 FR 44054, July 26, 1979) test guidelines and EPA's Good Laboratory Practice Standards (44 FR 27334, May 9, 1979; 44 FR 44054, July 26, 1979).

(d) Notice of proposed rulemaking on exemption policy and procedures.

(e) Final reimbursement policy and procedures.

(2) Support Documents consisting of:

(a) Hydroquinone/Quinone technical suppport document.

(b) Quinone economic analysis support document.

(3) Communications before proposal consisting of:

(a) Written public comments.

(b) Summaries of telephone conversations.

(c) Meeting summaries.

(d) Reports—published and unpublished factual materials, including contractors' reports.

(4) Report—Chemical Testing Industry: Profile of Toxicological Testing. October, 1981.

VII. Classification of Rule

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and, therefore, subject to the requirement of a Regulatory Impact Analysis. This test rule is not major becaue it does not meet any of the criteria set forth in section 1(b) of the Order. First, the actual annual cost of the testing proposed for quinone is less than $253,000 over the testing and reimbursement period. Second, because the cost of the testing will be distributed over a large production volume, the rule will have only very minor effects (annualized unit costs are less than 1.4 cents per pound) on producers' costs or users' prices for this chemical substance. Finally, taking into account the nature of the market for this substance, the low level of costs involved, and the expected nature of the mechanisms for sharing the costs of the required testing, EPA concludes that there will be no significant adverse economic impact of any type as a result of this rule.

This proposed regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any comments from OMB to EPA, and any EPA response to those comments, will be included in the public record.

VIII. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (15 U.S.C. 601, *et seq.*, Pub. L. 96-354, September 19, 1980), EPA is certifying that this test rule, if promulgated, will not have a significant impact on a substantial number of small businesses for the following reasons:

1. Small processors will not perform testing themselves and will not participate in the organization of the testing effort.

2. Small processors will experience only minor costs in securing exemption from testing requirements.

3. Small processors are unlikely to be affected by reimbursement requirements.

4. There are no small manufacturers quinone.

IX. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the OMB under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* Comments on these requirements should be submitted to the Office of Information and Regulatory Affairs of OMB marked Attention: Desk Officer for EPA. The final rule package will respond to any OMB or public comments on the information collection requirements.

X. Guidelines and Study Plans

The following guidelines and/or study plans cited in this proposed test rulemaking are available from the: National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, (703-487-4650).

NTIS publication No.	Title	Price
PB 82-140773	Chemical Testing Industry: Profile of Toxicological Testing.	$16.00
PB 82-232984	TSCA Health Effects Guidelines.	40.00
PB 82-232992	Environmental Effects Guidelines.	60.00

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NTIS publication No.	Title	Price
PB 83-153906	OECD Test Guidelines for Hazard Evaluation: Wildlife and Aquatic Organisms.	17.50
PB 83-153916	FIFRA Pesticides Registration Guidelines: Proposed Data Requirements for Hazard Evaluation: Human and Domestic Animals.	11.50
PB 82-233006	TSCA Chemical Fate	40.00

List of Subjects in 40 CFR Part 799

Testing, Environmental protection, Hazardous material, Chemicals.

(Sec. 4, Pub. L. 94-469, 90 Stat. 2003; (15 U.S.C. 2061))

Dated: December 23, 1983.

Alvin L. Alm,

Acting Administrator.

PART 799—[AMENDED]

Therefore, it is proposed that a new § 799.3600 be added to Subpart B of proposed Part 799 to read as follows:

§ 799.3600 Quinone.

(a) *Identification of test substance.* (1) Quinone (CAS No. 106-51-4) shall be tested in accordance with this section.

(2) Quinone of at least 99 percent purity shall be used as the test substance in all tests.

(b) *Persons required to submit study plans, conduct tests and submit data.* (1) All persons who manufacture or process quinone from the effective date of this rule (30 days from the publication date of the final rule in the **Federal Register** to the end of the reimbursement period shall submit letters of intent to test, exemption applications and study plans and shall conduct tests and submit data as specified in paragraphs (c), (d), (e), (h), (i), (j), and (k) of this section.

(2) Any person subject to the requirements of this section may apply to EPA for an exemption from study plan submission and testing requirements. Any such application shall be in accordance with paragraph (h) of this section.

(c) *Submission of notice of intent to test or exemption application.* (1) No later than 30 days after the effective date of this section, each person manufacturing quinone as of the effective date of this section must, for each test required by paragraphs (i), (j), and (k) of this section, either notify EPA by letter of its intent to perform the test or submit an application for an exemption from the study plan submission and testing requirements for the test.

(2) If, by the date specified in paragraph (c)(1) of this section, no manufacturer of quinone has notified EPA of its intent to perform testing for a test required by paragraphs (i), (j), or (k) of this section, EPA will publish a notice in the **Federal Register** of this fact specifying the tests for which no notice of intent has been submitted. No later than 30 days after publication of such a notice, each person processing quinone as of the effective date of this section must, for each test specified in the **Federal Register** notice, either notify EPA by letter of its intent to perform the test or submit an application for an exemption from study plan submission and testing requirements for the test.

(3) Any person not manufacturing quinone as of the effective date of this section, who before the end of the reimbursement period manufactures quinone, must comply with the requirements of paragraphs (c)(1) and (d)(1) of this section. For purposes of this paragraph (c)(3), the manufacturer must submit the notice of intent to test or exemption application required by paragraph (c)(1) of this section by the date manufacture begins and must submit any proposed study plan required by paragraph (d)(1) of this section within 60 days of the date manufacture begins.

(4) If a **Federal Register** notice has been published under paragraphs (c)(2) or (d)(4) of this section, any person not processing quinone as of the effective date of this section, who before the end of the reimbursement period processes quinone, must comply with the requirements of paragraphs (c)(2) and (d)(2) of this section. For purposes of this paragraph (c)(4), the processor must submit the notice of intent to test or exemption application required by paragraph (c)(2) of this section by the date processing begins and must submit any proposed study plan required by paragraph (c)(2) of this section within 60 days of the date processing begins.

(5) Any manufacturer or processor of quinone which has notified EPA under paragraphs (c)(1), (c)(2), (c)(3), or (c)(4) of this section of its intent to perform testing for a test required by paragraphs (i), (j), or (k) of this section, must submit a proposed study plan for the test and must perform that test in accordance with the test standards in paragraph (l) of this section.

(d) *Submission of proposed study plans.* (1) Manufacturers of quinone which notify EPA under paragraph (c)(1) of this section that they intend to perform a test must submit a proposed study plan for the test in accordance with paragraph (e) of this section no later than 90 days after the effective date of this section. Manufacturers may jointly submit a single proposed study plan if they plan to sponsor or perform the test jointly. Any manufacturer which, having notified EPA of its intent to perform a test, fails to submit a proposed study plan for that test will have been in violation of this section as if no letter of intent to perform the test had been submitted.

(2) Processors of quinone which notify EPA under paragraph (c)(2) of this section that they intend to perform a test must submit a proposed study plan for the test in accordance with paragraph (e) of this section no later than 90 days after the publication of the notice specified in paragraph (c)(2) of this section. Processors may jointly submit a single proposed study plan if they plan to sponsor or perform the test jointly. Any processor, which, having notified EPA of its intent to perform a test, fails to submit a proposed study plan for that test will have been in violation of this section as if no letter of intent to perform the test had been submitted.

(3) If EPA determines in accordance with paragraph (f)(1)(i) of this section that a proposed study plan is incomplete and the manufacturer or processor has not, after notice from EPA, submitted appropriate information to make the study plan complete within 15 days, the manufacturer or processor will have been in violation of this section as if no letter of intent to perform the test had been submitted.

(4) If either:

(i) By the date specified in paragraph (d)(1) of this section a manufacturer of quinone, which notified EPA of its intent to perform a test, has failed to submit a proposed study plan for that test, or

(ii) A proposed study plan submitted under paragraph (d)(1) of this section has been found to be incomplete under paragraph (f)(1)(i) of this section and the manufacturer has not submitted appropriate information to make the study plan complete within 15 days, EPA will publish a notice in the **Federal Register** of this fact specifying the test. The requirements of paragraphs (c)(2) and (d)(2) of this section for processors to submit letters of intent to perform testing, applications for exemption, and proposed study plans will apply.

(5) If either:

(i) By the date specified in paragraph (c)(2) of this section no processor of quinone has notified EPA of its intent to perform testing for any test identified in a **Federal Register** notice published under paragraphs (c)(2) or (d)(4) of this section,

(ii) By the data specified in paragraph (d)(2) of this section any processor of quinone, which notified EPA of its intent to perform a test, has failed to submit a proposed study plan for that test, or

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(iii) A proposed study plan submitted under paragraph (d)(2) of this section has been found to be incomplete under paragraph (f)(1)(i) of this section and the processor has not submitted appropriate information to make the study plan complete within 15 days, all applications for exemption from the requirements to submit study plans and to perform tests for the specific test involved will automatically be denied. EPA will notify each manufacturer and processor of quinone, which applied for an exemption for the specific test involved, of this automatic denial either by letter or by notice in the Federal Register. Each manufacturer or processor of quinone for whom an exemption application has been automatically denied will be in violation of this section 30 days from the time that it receives the notice letter or 30 days from the time that the notice is published in the Federal Register, whichever comes first. The violation will continue until a manufacturer or processor of quinone submits a proposed study plan for each test involved.

(6) Any manufacturer or processor of quinone may submit a proposed study plan for any test required by this section at any time, regardless of whether the manufacturer or processor previously submitted an application for exemption from testing for that test.

(e) *Content of study plans.* (1) All study plans are required to contain the following information: (i) A citation to this section

(ii) The specific test covered by the study plan.

(iii)(A) The names and addresses of the test sponsors.

(B) The names, addresses and telephone numbers of the responsible administrative officials and project manager(s) in the principal sponsor's organization.

(C) The name, address, and telephone number of the appropriate individual(s) for oral and written communications with EPA.

(D)(*1*) The name and address and telephone number of the testing facility including administrative officials and project manager(s) respensible for this testing.

(*2*) Brief summaries of the training and experience of each professional involved in the study including study director, veterinarian(s), toxicologist(s), pathologist(s) and laboratory assistants.

(iv) Identity and data on the chemical substance being tested including appropriate physical constants, spectral data, chemical analysis, and stability under test and storage conditions.

(v) Study protocol, including rationale for: species/strain selection; dose selection (and supporting data); route(s) or method(s) of exposure; a description of diet to be used and its source, including nutrients and contaminants and their concentrations; for *in vitro* test systems, a description of culture medium and its source; and a summary of expected spontaneous chronic diseases (including tumors), genealogy, and life span.

(vi) Schedule for initiation and completion of major phases of long term tests; schedule for submission of interim progress and final reports to EPA.

(2) Information specified under paragraph (e)(1)(iii)(D) of this section is not required in proposed study plans if the information is not available at the time of submission; however, the information must be submitted before the initiation of testing.

(f) *Review and adoption of study plans.* (1) Upon receipt of a proposed study plan, EPA will review the study plan to determine whether it complies with paragraph (e) of this section.

(i) If EPA determines that the proposed study plan does not comply with paragraph (e) of this section, EPA will notify the submitter that the submission is incomplete and will identify the deficiencies and the steps necessary to complete the submission. The submitter will have 15 days from the day it receives this notice to submit appropriate information to make the study plan complete. If the submitter fails to provide appropriate information to complete the study plan within this time, the submitter will have been in violation of this section as if no study plan had been submitted.

(ii) If EPA determines the proposed study plan complies with paragraph (e) of this section, EPA will publish a notice in the Federal Register requesting comments on the ability of the study plan to ensure that data from the test will be reliable and adequate. EPA will provide a 45-day comment period and will provide an opportunity for an oral presentation upon the request of any person. EPA may extend the comment period if it appears from the nature of the issues raised by EPA's review or from public comments that further comment is warranted.

(2) After receiving and considering public comment, EPA will adopt the study plan, including the time deadlines and reporting schedules, as proposed or as modified in response to EPA review and public comments, as test standards for the testing of quinone in paragraph (1) of this section.

(g) *Modification of study plans during conduct of study*—(1) *Application.* Any test sponsor who wishes to modify the adopted study plan for any test required under this section must submit an application in accordance with this paragraph. Application for modification shall be made in writing to the Chief, Test Rules Development Branch, Office of Toxic Substances, or by phone, with written confirmation to follow as soon as feasible. Applications must include appropriate explanation of why the modification is necessary.

(2) *Adoption.* To the extent feasible, EPA will seek comment on all substantive changes in study plans. EPA will issue a notice in the Federal Register requesting comments on requested modifications. However, EPA will act on the requested modification without seeking public comment if either: (i) EPA believes that an immediate modification to a study plan is necessary in order to preserve the accuracy or validity of an on-going study, or

(ii) EPA determines that a modification clearly does not pose any significant substantive issues. EPA will notify the sponsor of the EPA's approval of disapproval. When EPA approves a modification, it will publish a notice in the Federal Register indicating that the study plan has been modified.

(h) *Exemption applications.* (1) Any manufacturer or processor of quinone may submit an application to EPA for exemption from submitting proposed study plans for, and from performing, any or all of the tests specified in paragraphs (i), (j), and (k) of this section. The application must include the name and address of the manufacturer or processor and must identify the specific requirements of the section from which the exemption is sought.

(2) No manufacturer or processor of quinone will be in violation of the requirement to perform a specific test under paragraphs (i), (j), or (k) of this section if it has submitted a timely application for an exemption for that test and the application has not been denied by EPA.

(3) EPA will conditionally grant any requested exemption for a specific test required by paragraphs (i), (j), or (k) of this section if EPA has received a complete proposed study plan for that test in accordance with paragraph (e) of this section and has adopted the study plan in accordance with paragraph (f)(2) of this section.

(4) EPA will deny any exemption for a specific test in paragraphs (i), (j), or (k) of this section if the study sponsor fails to perform the test or to submit data as required in the test standards adopted under paragraph (l) of this section.

(5) If manufacturers of quinone perform all the tests required by

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paragraphs (i), (j), or (k) of this section, processors of quinone will automatically be granted an exemption from the study plan submission and testing requirements without the need to file an application for exemption.

(i) *Health effects testing*—(1) *Carcinogenicity*—

(i) *Required testing.* A two-year oncogenicity bioassay, with inhalation as the route of exposure, shall be conducted with quinone.

(ii) *Study plans.* For guidance in preparing study plans, the TSCA Health Effects Guidelines for Chronic Exposure—Oncogenicity, published by NTIS (PB 82–232984), should be consulted. Additional guidance may be obtained from the OECD Test Guidelines for Health Effects, and the FIFRA Pesticides Registration Guidelines: Proposed Data Requirements for Hazard Evaluation: Human and Domestic Animals, published by NTIS (PB 83–153916).

(j) *Chemical fate testing*—(1) *Aerobic biodegradation.* (i) *Required testing.* An aerobic biodegradation test shall be conducted with quinone using natural waters representative of aquatic environments that may be exposed to quinone. Transformation of quinone may be determined using either compound-specific analytical techniques or radiolabeled test compound. Regardless of the analytical method chosen, it shall be adequate to determine both disappearance of parent compound and the extent of interconversion of hydroquinone and quinone.

(ii) *Study plans.* EPA has not published guidelines for this type of biodegradation test. However, any natural waters die-away or similar test methods should be suitable, provided that it meets the requirements set forth above. Examples of methods that may be used to develop an accepable study plan are described in Saeger, V.W. and Tucker, E.S., Biodegradation of Phthalic Acid Esters in River Water and Activated Sludge. Applied Environmental Microbiology 31, 29–34 (1976), and Spain, J.C., Pritchard, P.H. and Bourquin, A.W., Effects of Adaptation Rates in Sediment/Water Cores from Estuarine and Freshwater Environments, Applied Environmental Microbiology 40 726–734 (1980).

(k) *Environmental effects testing*—(1) *Aquatic freshwater acute toxicity*—(i) *Required testing.* Acute toxicity tests shall be conducted with quinone with freshwater animals in eight different species provided that of the eight species:

(A) At least one is a salmonid fish.

(B) At least one is a non-salmonid fish.

(C) At least one is a planktonic crustacean.

(D) At least one is a benthic crustacean.

(E) At least one is a benthic insect.

(F) At least one is a benthic species.

(ii) *Study plans.* For guidance in preparing study plans, the TSCA Environmental Effects Test Guidelines for acute toxicity testing, published by NTIS (PB 82–232992), should be consulted. Additional guidance may be obtained by consuting the OECDS Test Guidelines for Effects on Biotic Systems, the FIFRA Guidelines for Hazard Evaluation: Wildlife and Aquatic Organisms (PB 83–153908), and the Water Quality Criteria Guidelines (45 FR 79341).

(2) *Aquatic freshwater chronic toxicity*—(i) *Required testing.* Chronic toxicity tests shall be conducted with quinone for three species of aquatic animals provided that of the three species:

(A) At least one is a fish.

(B) At least one is an invertebrate.

(C) At least one is a freshwater species (the other two may be saltwater species).

(ii) *Study plans.* For guidance in preparing study plans, the TSCA Environmental Effects Test Guidances for chronic toxicity testing, published by NTIS (PB 82–232992), should be consulted. Additional guidance may be obtained by consulting the FIFRA Guidelines for Hazard Evaluation: Wildlife and Aquatic Organisms (PB 83–153908) and the Water Quality Criteria Guidelines, published in the Federal Register on November 28, 1980 (45 FR 79341).

(3) *Aquatic freshwater plants*—(i) *Required testing.* Testing shall be conducted with quinone with a freshwater alga, or a chronic test shall be conducted with quinone with a freshwater vascular plant.

(ii) *Study plans.* For guidance in preparing test study plans, that the TSCA Environmental Effects Test Guidelines for algal and macrophytic toxicity testing, published by NTIS (PB 82–232992), should be consulted. Additional guidance may be obtained by consulting the FIFRA Guidelines for Hazard Evaluation: Wildlife and Aquatic Organisms (PB 83–153908), the OECD Test Guidelines for Effects on Biotic Systems, and the Water Quality Criteria Guidelines (45 FR 79341).

(4) *Freshwater bioconcentration testing*—(i) *Required testing.* A bioconcentration factor test shall be conducted with guinone with a freshwater aquatic animal species.

(ii) *Study plans.* For guidance in preparing study plans, the TSCA Environmental Effects Test Guidelines, published by NTIS (PB 82–232992), should be consulted. Additional guidance may be obtained by consulting the FIFRA Guidelines for Hazard Evaluation: Wildlife and Aquatic Organisms (PB 83–153908), the OECD Test Guidelines for Degradation and Accumulation, and the Water Quality Criteria Guidelines (45 FR 79341).

(5) *Aquatic saltwater acute toxicity*—(i) *Required testing.* Acute toxicity tests shall be conducted with quinone with saltwater animals in eight different species provided that, of the eight species:

(A) At least two different fish families are included.

(B) At least five different invertebrate families are included.

(C) Either the Mysidae or Penaeidae family or both are included.

(D) At least one of the invertebrate families is in a phylum other than Arthropoda.

(ii) *Study plans.* For guidance in preparing study plans, the TSCA Environmental Effects Test Guidelines for acute toxicity testing, published by NTIS (PB 82–232992), should be consulted. Additional guidance may be obtained by consulting the OECD Test Guidelines for Effects on Biotic Systems, the FIFRA Guidelines for Hazard Evaluation: Wildlife and Aquatic Organism (PB 83–153908), and the Water Quality Criteria Guidelines (45 FR 79341).

(6) *Aquatic saltwater chronic toxicity*—(i) *Required testing.* Chronic toxicity tests shall be conducted with quinone for three species of aquatic animals provided that of the three species:

(A) At least one is a fish.

(B) At least one is an invertebrate.

(C) At least one is a saltwater species (the other two may be freshwater species).

(ii) *Study plans.* For guidance in preparing study plans, the TSCA Environmental Effects Test Guidelines for chronic toxicity testing, published by NTIS (PB 82–232992), should be consulted. Additional guidance may be obtained by consulting the FIFRA Guidelines for Hazard Evaluation: Wildlife and Aquatic Organisms (PB 83–153908) and the Water Quality Criteria Guidelines (45 FR 79341).

(7) *Aquatic saltwater plants*—(i) *Required testing.* Testing shall be conducted with quinone with a saltwater alga, or a chronic test shall be conducted with quinone with a saltwater vascular plant.

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(ii) *Study plans.* For guidance in preparing study plans, the TSCA Environmental Effects Test Guidelines for algal and macrophytic toxicity testing, published by NTIS (PB 82-232992 and PB 83-257709), should be consulted. Additional guidance may be obtained by consulting the FIFRA Guidelines for Hazard Evaluation: Wildlife and Aquatic Organisms (PB 83-153908), the OECD Test Guidelines for Effects on Biotic Systems, and the Water Quality Criteria Guidelines.

(8) *Saltwater bioconcentration testing*—(i) *Required testing.* A bioconcentration factor test shall be conducted with a saltwater aquatic animal species.

(ii) *Study plans.* For guidance in preparing study plans, the TSCA Environmental Effects Test Guidelines published by NTIS (PB 82-232992), should be consulted. Additional guidance may be obtained by consulting the FIFRA Guidelines for Hazard Evaluation: Wildlife and Aquatic Organisms (PB 83-153908), the OECD Test Guidelines for Degradation and Accumulation, and the Water Quality Criteria Guidelines.

(l) *Test standards.* (1) Sponsors and testing facilities must adhere to the EPA Good Laboratory Practice Regulations in Part 792 of this chapter.

(m) *Enforcement.* (1) If a manufacturer or processor, which notified EPA under paragraph (c)(1), (2), (3) or (4) of this section of its intent to perform testing for a test required by paragraphs (i), (j) or (k) of this section, fails to perform the test in accordance with the test standards in paragraph (l) of this section, that failure will be a violation of this section.

(2) EPA will publish a notice in the Federal Register to inform all manufacturers and processors that all exemptions for performance of that test will be denied unless, within 30 days of the publication of the notice, a manufacturer or processor of quinone notifies EPA by letter that it intends to perform that test in accordance with the test standards in paragraph (l) of this section.

(3) Any person who fails or refuses to comply with any aspect of this section is in violation of section 15 of the Act.

(n) *Availability.* The TSCA and FIFRA guidelines for the various study plans are available from the National Technical Information Service (NTIS). Address and telephone number: National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703-487-4650).

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